



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,899	11/20/2003	Ron L. Hale	00068.01R	4055
37485 7590 12/12/2007 SWANSON & BRATSCHUN, L.L.C 8210 SOUTHPARK TERRACE LITTLETON, CO 80120			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,899

Applicant(s)

HALE ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,41,43,45-51,53,55,57,59,61,63,65-72 and 74-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,41,43,45-51, 53, 55, 57, 59, 61, 63, 65-72, 74-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/17/07 has been entered.

Receipt is acknowledged of Amendments, Remarks and Terminal Disclaimer filed on 09/17/07. Claims 39, 43, 59, 67, 77 and 80 have been amended and new claims 81-95 have been added. Claims 40, 42, 44, 52, 54, 56, 58, 60, 62, 64 and 73 have been cancelled. Accordingly, claims **39, 41, 43, 45-51, 53, 55, 57, 59, 61, 63, 65-72, 74-95** are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Claims **39, 41, 43, 45-51, 53, 55, 57, 59, 61, 63, 65-72, 74-95** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. listed below in view of Physician's Desk Reference. The said patents have been found to claim substantially similar subject matter per the obviousness-type double patenting rejections made above in the instant office action, especially with regards to compositions and methods of making drug condensation aerosols. The only difference is the active agents contained in the said formulations. For example, US Patent No. 6,780,400 and 7,022,312 recite formulations comprising active agents such as dolasetron, granisetron and metoclopramide. US Patent No. 6,716,415 recites active agents such as zaleplon, zolpidem, zopiclone. US Patent No. 7,060,254 recites active agents such as bupropione, perphenazine, fluoxetine, etc. Furthermore, it appears that the invention is the condensate compositions and the method of making them. Thus it is considered that the substitution of one active agent for another does not alter the scope of the said claims. Therefore, the claims would have been obvious to one of ordinary skill in the art at the time of the invention because the substitution of one known element for another would have yielded predictable results. In other words, they are obvious variations of each other.

Application/Control Number:
10/719,899
Art Unit: 1616

Page 4

U.S. Patent Number	U.S. Patent Number	U.S. Patent Number
1. 6,805,853 (Patent)	27. 7,045,118 (Patent)	53. 7,078,019 (Patent)
2. 6,994,843 (Patent)	28. 7,052,679 (Patent)	54. 7,078,020 (Patent)
3. 6,780,399 (Patent)	29. 7,033,575 (Patent)	55. 7,087,216 (Patent)
4. 6,743,415 (Patent)	30. 7,018,620 (Patent)	56. 7,087,217 (Patent)
5. 6,716,415 (Patent)	31. 7,048,909 (Patent)	57. 7,060,254 (Patent)
6. 6,780,400 (Patent)	32. 7,005,122 (Patent)	58. 7,070,763 (Patent)
7. 6,783,753 (Patent)	33. 7,048,909 (Patent)	59. 7,169,378 (Patent)
8. 6,716,416 (Patent)	34. 7,115,250 (Patent)	60. 7,070,765 (Patent)
9. 7,063,830 (Patent)	35. 7,045,119 (Patent)	61. 7,070,766 (Patent)
10. 6,740,307 (Patent)	36. 7,018,621 (Patent)	62. 7,008,616 (Patent)
11. 6,797,259 (Patent)	37. 7,011,819 (Patent)	63. 7,067,114 (Patent)
12. 6,814,954 (Patent)	38. 7,014,840 (Patent)	64. 7,008,615 (Patent)
13. 6,803,031 (Patent)	39. 7,022,312 (Patent)	65. 7,181,039 (Patent)
14. 6,740,308 (Patent)	40. 7,014,841 (Patent)	66. 7,070,764 (Patent)
15. 6,776,978 (Patent)	41. 6,994,843 (Patent)	67. 6,884,408 (Patent)
16. 6,740,309 (Patent)	42. 7,063,832 (Patent)	
17. 6,814,955 (Patent)	43. 7,052,680 (Patent)	
18. 6,716,417 (Patent)	44. 7,078,016 (Patent)	
19. 6,737,043 (Patent)	45. 7,108,847 (Patent)	
20. 6,759,029 (Patent)	46. 7,087,218 (Patent)	
21. 6,855,310 (Patent)	47. 7,070,761 (Patent)	
22. 6,805,854 (Patent)	48. 7,022,312 (Patent)	
23. 7,029,658 (Patent)	49. 7,070,764 (Patent)	
24. 7,070,762 (Patent)	50. 7,094,392 (Patent)	

25. 7,018,619 (Patent)	51. 7,078,017 (Patent)		
26. 7,005,121 (Patent)	52. 7,078,018 (Patent)		

Claims **39, 41, 43, 45-51, 53, 55, 57, 59, 61, 63, 65-72, 74-95** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. copending Application Nos. listed below in view of Physician's Desk Reference. The said co-pending Applications have been found to claim substantially similar subject matter per the obviousness-type double patenting rejections made above in the instant office action, especially with regards to compositions and methods of making drug condensation aerosols. The only difference is the active agents contained in the said formulations. For example, co-pending Application No. 11/439,475 recite formulations comprising active agents such as atenolol, pindolol, esmolol, etc. Co-pending Application No. 11/479,509 recite formulations comprising active agents such as chlordiazepoxide, betahistine, clonidine, etc. Co-pending Application No. 11/501,246 recite formulations comprising active agents such as indomethacine, ketoprofen, elecoxib, etc. Furthermore, it appears that the invention is the condensate compositions and the method of making them. Thus it is considered that the substitution of one active agent for another does not alter the scope of the said claims. Therefore, the claims would have been obvious to one of ordinary skill in the art at the time of the invention because the substitution of one known element for another would have yielded predictable results. In other words, they are obvious variations of each other.

Application/Control Number:
10/719,899
Art Unit: 1616

Page 6

U.S. Application Number	U.S. Application Number
1. 11/439,475 (Appl.) US 20060216243	11. 11/523,685 (Appl.) US 20070014737
2. 11/442,917 (Appl.) US 20060216244	12. 11/488,943 (Appl.) US 20060257329
3. 11/451,852 (Appl.) US 20060233718	13. 11/500,736 (Appl.) US 20060269486
4. 11/451,853 (Appl.) US 2006023719	14. 11/501,246 (Appl.) US 20060269487
5. 11/370,628 (Appl.) US 20060153779	15. 11/479,361 (Appl.) US 20060246011
6. 11/479,361 (Appl.) US 20060246011	16. 11/454,573 (Appl.) US 20060239936
7. 11/479,509 (Appl.) US 20060246012	17. 11/385,992 (Appl.) US 20060233717
8. 11/398,383 (Appl.) US 20060177382	18. 10/633,876 (Appl.) US 20070028916
9. 11/481,279 (Appl.) US 20060251588	19. 11/501,246 (Appl.) US 20060269487
10. 11/488,302 (Appl.) US 20060257328	20. 11/500,735 (Appl.) 20060286042

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 09/17/07 have been fully considered but they are not persuasive. Applicants have filed terminal disclaimers over the following U.S. patents (see page 12 of remarks): (a) 6,682,716, (b) 7,090,830 and U.S. Applications 11/504,419 and 10/696,959. The said Terminal Disclaimers have been approved and entered.

Applicant argues that the rejections under obviousness type double patenting are not according to rules set in MPEP § 804 because the differences between the inventions have not clearly been stated and also when considering obviousness type double patenting, the disclosure of the patent may not be used as prior art. This is not persuasive because the differences between the inventions have clearly been stated. Since the number of involved patents and co-pending applications is large and it would have been a serious burden on the office to compare each and every patent or application to the instant invention, and because the claims are very similar in content, a sample group of patents and co-pending applications have been chosen as the basis for discussion and to show the differences and similarities. Thus it has been shown that the inventions are obvious variations of each other. The remaining patents and applications listed have the same issues and would be rejected under the same reasoning. It is also noted that the patent's disclosures **have not** been used as prior art for the said rejections. As Applicant has stated in their Remarks and seen above, the claims have been rejected under claims of the stated patent or co-pending application in view of Physician's Desk Reference.

Regarding the U.S. patents and patent applications cited in the above tables, Applicants have traversed these rejections and the need for submitting terminal disclaimers by arguing that the holding of *In re Vogel* is applicable to the instant claims and cited commonly owned patents and copending applications. Applicants have implied that the different volatilization temperatures of the various active substances in the claimed methods of the cited commonly owned patents and copending applications makes the substitution of one drug for another an unobvious modification that would make obviousness type double patenting rejections improper.

The Examiner respectfully disagrees. One of ordinary skill in the art at the time of the invention would be able to easily obtain or determine the volatilization temperature for each active drug substance. It does not appear that the device or the process utilized in Applicants' claimed process changes from one drug to another. Thus, temperature is not a critical or determining factor in the claimed processes. It is also noted that USPN 7,090,830 (USPN '830) lists approximately 620 drugs as being suitable for use with Applicants' device, which is necessary for generating condensation aerosols as claimed by Applicants. The drugs taught and claimed in USPN '830, represent a genus comprising an extremely divergent collection of structurally diverse chemical compounds indicated in the prior art for the treatment of a large number of unrelated diseases. Claims of the U.S. Patent No. 7,090,830 list about 245 different drugs as being exemplary heat-stable drugs for use in the generation of the claimed condensation aerosols. In filing the instant application or any one of the applications/patents cited in the above table, Applicants have merely substituted one

drug for another. This merely represents the substitution of one known element (i.e. drug) for another, which would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The Supreme Court has recently held that the substitution of a known element for another known element in a manner that would yield predictable results represents an obvious modification (See KSR International CO. v. TELEFLEX INC. et al. 550 U.S._(2007)).

Thus, it is concluded that a prima facie case of obviousness for rejections based on the judicially created doctrine of obviousness-type double patenting over the various U.S. patents and copending applications cited in the above table remains proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/719,899
Art Unit: 1616

Page 10

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mina Haghighatian
Patent Examiner
December 10, 2007